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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,628	04/27/2001	Joseph Roberts	023032/0108	9388
22428	7590	07/28/2004	EXAMINER	
FOLEY AND LARDNER			BROWN, TIMOTHY M	
SUITE 500			ART UNIT	
3000 K STREET NW			PAPER NUMBER	
WASHINGTON, DC 20007			1648	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/842,628	<b>Applicant(s)</b> ROBERTS ET AL.	
	<b>Examiner</b> Tim Brown	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) 24-30 and 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

This Non-Final Office Action is responsive to Applicants' reply received May 20, 2004.

Applicants' election without traverse of the invention of Group IV, claims 51-57 is acknowledged. Claims 24-30 and 47-57 are pending. Claims 24-30 and 47-50 are withdrawn from consideration. Claims 51-57 have been examined.

#### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 51-57 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 and 17 of U.S. Patent No. 6,312,939. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 51-57 are drawn to an obvious method of using the recombinant microorganism of the patent. Claims 51-57 are drawn to a method for producing glutaminase comprising the steps of culturing *e. coli* transformed with 7-alpha *pseudomonas* glutaminase, and collecting translated 7-alpha *pseudomonas* glutaminase protein. On the other hand, claims 1-11 and 17 of

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the patent are directed to an *e. coli* cell that has been transformed with 7-alpha pseudomonas glutaminase. It is well within the knowledge generally available to the skilled artisan to use cell culture to obtain specific proteins from recombinant microorganisms. Therefore, it would have been obvious to apply the recombinant *e. coli* cell of claims 1-11 and 17 to the production recombinant 7-alpha glutaminase.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite in the recitation of “therapeutically suitable glutaminase.” This language fails to set forth the distinct physical features and/or properties of the claimed glutaminase since “therapeutically suitable” could describe a lack of adverse side effects, or a specific efficacy. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 51-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Ikura (JP 01300889).**

Ikura teaches a method of producing a therapeutically suitable glutaminase comprising: culturing a recombinant e-coli which comprises a nucleotide sequence that codes for a therapeutically suitable glutaminase; and collecting said therapeutically suitable glutaminase produced by said microorganism (~~see bottom of left column, p. 10632~~).

Note that for purposes of this art rejection, the term “therapeutically suitable” has been interpreted as meaning immunologically compatible with the subject of the study. That is, Ikura’s glutaminase would not produce an adverse reaction if it were administered to the mammals which were the source for the original glutaminase cDNA.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

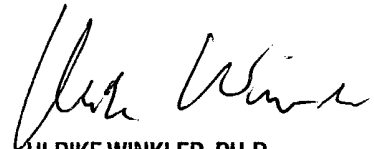
If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown  
Examiner  
Art Unit 1648

tb

  
ULRIKE WINKLER, PH.D.  
PRIMARY EXAMINER 7/26/04